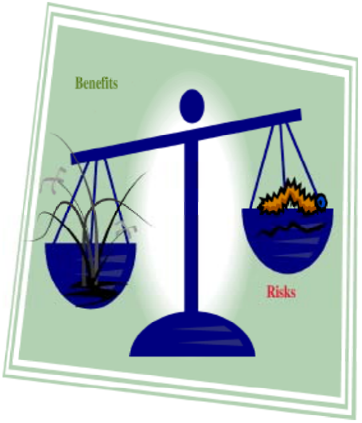
USDA-ARS 2nd International Biosafety & Biocontainment Symposium: Agricultural Research and Response for Field and Lab. February 4-7, 2013, Hotel Alexandria Mark Center, Alexandria, Virginia. Session II: Containment and Research Challenges for Work on Plant Pathogens, Pests, GMOs, and Biological Control Agents.



Biological Control Risk Analysis

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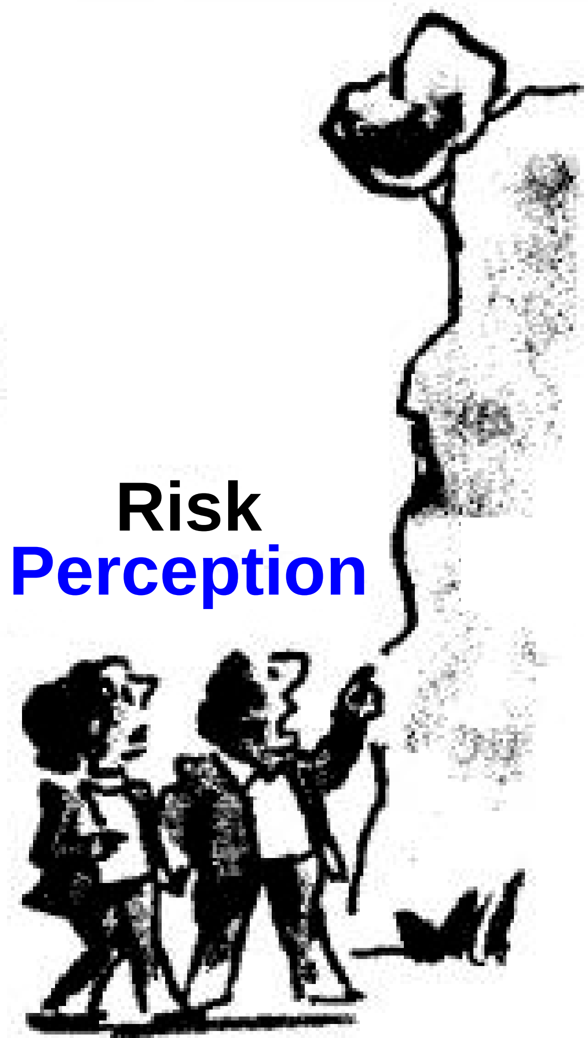
Goals

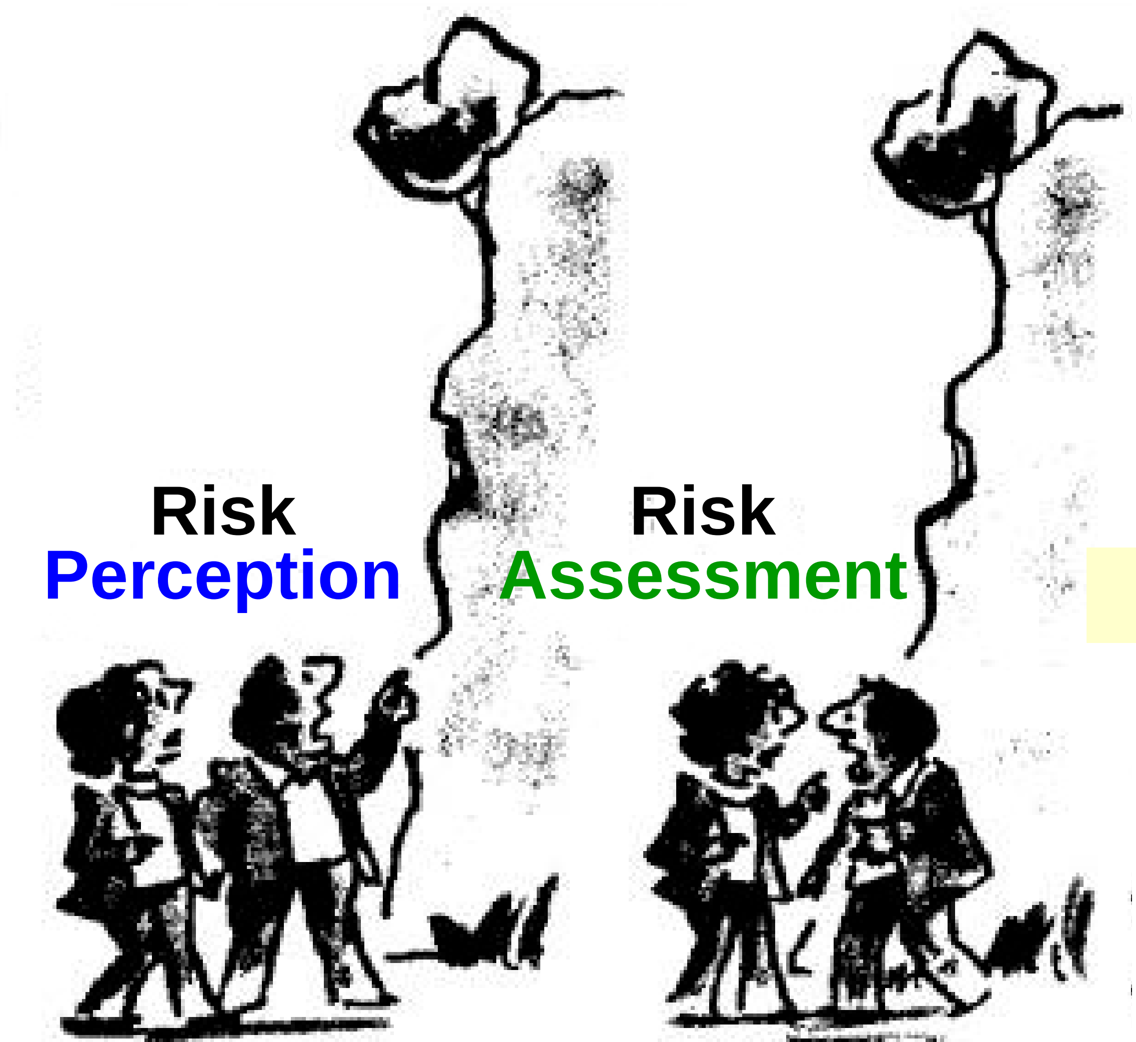
1. To provide a conceptual model for risk analysis; and
2. To develop a complex example.

One Risk Model . . .

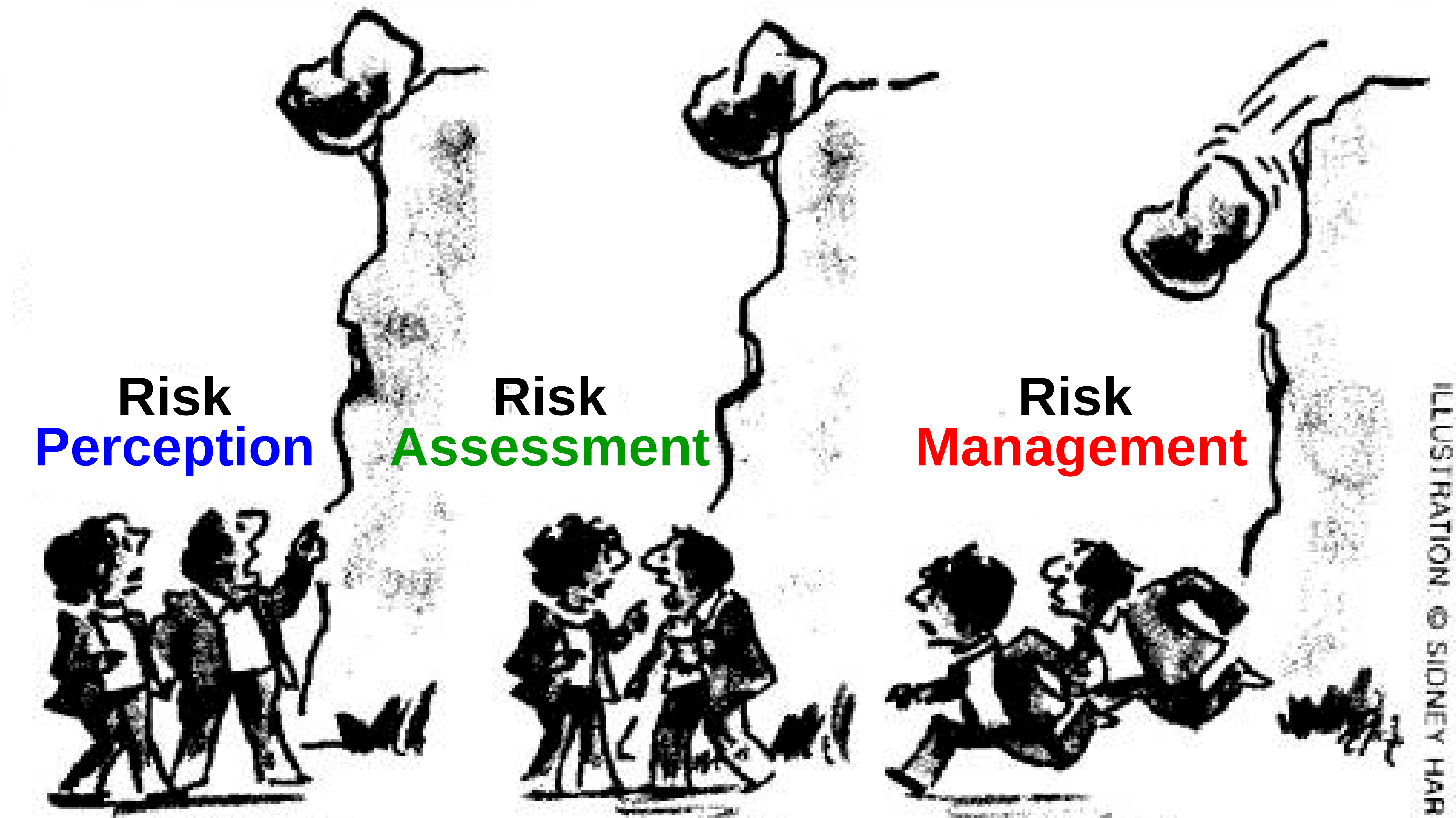


Risk Perception

One Risk Model . . .



One Risk Model . . .



What is Biological Control?

- The use of living natural enemies (arthropods, nematodes, pathogens, etc.) to reduce the population level of invasive species.
- Biological control is not a panacea and is not risk-free.
- When practiced properly by trained professionals, biological control is safe and ethical, and can be extremely effective.

Bentley, J.W. and R.J. O'Neil. 1997. On the ethics of biological control of insect pests. *Agriculture and Human Values* 14: 283-89.
DeBach, P. 1974. *Biological Control by Natural Enemies*. Cambridge University Press, New York, NY, 323 p.
Delfosse, Ernest S. 2000. *Biological control: Important Tool for Managing Invasive Species. Agricultural Research* 48:2.
Huffaker, C.B. and P.S. Messenger (Eds.) 1976. *Theory and Practice of Biological Control*. Academic Press, New York, NY.

What is Risk? 1.

$$R = H \times E$$

- Where R= risk;
- H= hazard; and
- E= exposure.

Molak, V. 1977. *Fundamentals of Risk Analysis and Risk Management*. CRC Press, Boca Raton, Florida.
National Academy of Sciences. 1983. *Risk Assessment in the Federal Government: Managing the Process*. National Academy Press, Washington, DC.
Sutter, G.E. 1993. *Ecological Risk Assessment*. CRC Lewis Publishers, Boca Raton, Florida.

R = H x E, but for biological control,

- What is hazard;
- What is exposure; and
- How are they measured?

Delfosse, Ernest S. 2005. Risk and ethics in biological control. *Biological Control* 35: 319-29.

Hazard or Exposure?

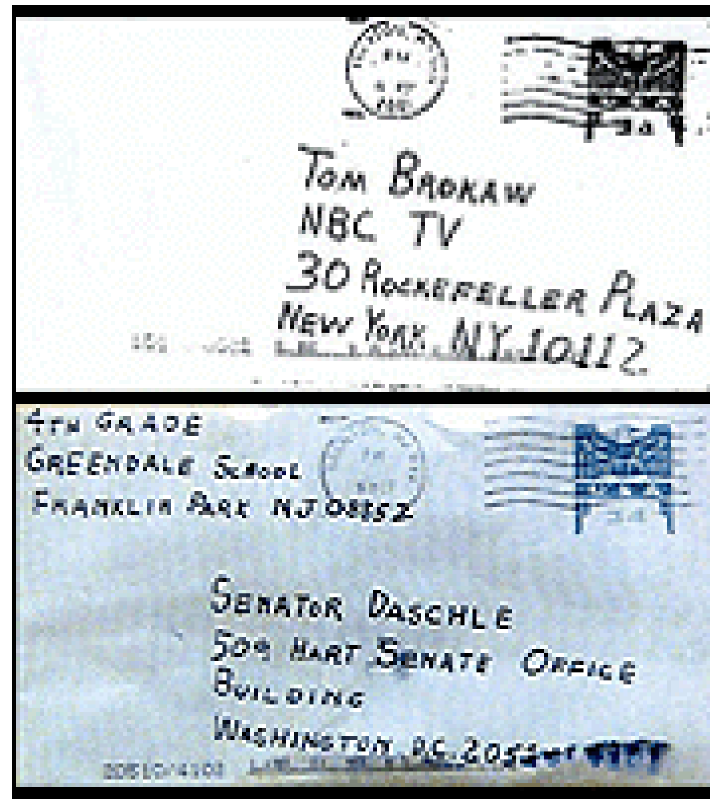
- **Hazard is *the ability to cause harm*, and is an *innate characteristic* of the taxon; but**
- **The *expression* of potential harm is mediated by environmental factors.**

Hazard Categories

- **Potential host range;**
- **Basic biological features;**
- **Toxicity; and**
- **Capacity to interact with the environment.**

Familiarity and Hazard

- **Did the 2001 concern over anthrax (*Bacillus anthracis*) focus on hazard or exposure?**



AP/Justice Department

Envelopes of letters sent to NBC news anchor Tom Brokaw and Senator Majority Leader Tom Daschle that contained anthrax; both bear a Trenton, NJ, postmark (*USA Today*, 10/16/2001).

Familiarity and Hazard

- Once there is a public perception of understanding the hazard from, e.g., anthrax, the concern switches to the “risk of getting it”–the exposure!

Exposure

- **Exposure mediates the *potential harm*, through environmental factors ("sieves"); and**
- **Exposure acts upon hazard.**

So What?

- If there is no exposure, the risk is zero:

$$R = H \times 0 = 0$$

- Even though the hazard is still present, and may be quite high.

Exposure “Sieves”

- Susceptible hosts in the environment;
- Bridging species;
- Distribution;
- Phenology;
- Ecology;
- Behavior; and
- Climatic conditions.

Thus, risk becomes:

$$R = H_i \times E_p$$

- **Where H_i = Innate capacity to c*ause harm*; and**
- **E_p = Potential to *realize harm*, mediated by environmental sieves.**

Qualifiers

- Cage testing (physiological or innate host-specificity) *favors the biological agent*, measuring the maximum expression of hazard; and
- Environment (ecological or realized host-specificity, mediated through sieves) *favors the potential non-target hosts*, and restricts the expression of hazard.

$$R = H_i \times E_p$$

Innate Characteristics	Environmental Sieves

Innate Characteristics

- Potential host range;
- Basic biological features;
- Toxicity; and
- Capacity to interact with the environment.

Environmental Sieves

- Susceptible field hosts;
- Bridging species;
- Distribution;
- Phenology;
- Ecology;
- Behavior; and
- Climatic conditions.

$$R = H_i \times E_p$$

Innate Characteristics	Environmental Sieves
Potential host range; Basic biological features; Toxicity; and Capacity to interact with the environment.	Susceptible field hosts; Bridging species; Distribution; Phenology; Ecology; Behavior; and Climatic conditions.

What is Risk? 2.

1. Hazard x Exposure; and

2. The interaction of *innate characteristics* of a taxon and the *environmental features* (sieves) that mediate the interaction.

Do We Know Everything?

- The continuum of *innate characteristics* of a taxon (H_i) and *environmental sieves* (E_p) that mediate the potential harm are often not fully known.

Incomplete Information

- Incomplete information complicates objective estimates of risk because the nature and extent of hazard and exposure are not understood, so the subjective valuation of risk is biased, and usually overstated; or
- The "worst-case scenario."

What is Risk? 3.

1. Hazard x Exposure;
2. The interaction of *innate characteristics* of a taxon and *environmental features* (sieves) that mediate the interaction; and
3. A measure of the completeness of information.

How Good is Our Information?

- Reliability of information is usually a concern; and
- Thus, there is a degree of *uncertainty* about the process.

Wilson, R. and A. Shlyakhter. 1997. Uncertainty and variability in risk analysis. In: Molak, V. (Ed.) *Fundamentals of Risk Analysis and Risk Management*. CRC Press, Boca Raton, Florida, pp. 33-44.
Wilson, R., E.A.C. Crouch and L. Zeise. 1985. Uncertainty in risk assessment. In: Hoel, D.C., R.A. Merrill, and F.P. Perera (Eds.) Risk Quantification and Regulatory Policy. Branbury Report 19. Cold Spring Harbor Laboratory, New York.

Risk and Uncertainty

- **Risk is a relative concept commonly used when uncertainty can be quantified;**
- **Probabilities of possible outcomes are estimated (e.g., risk of damage to a non-target species from a biological control agent).**

Risk and Uncertainty

- "Acceptable risk" (such as minimal attack on non-target species) is used when uncertainty is quantified to the subjective satisfaction of a viewer; and
- Uncertainty is measured by the deviation from "expected values" which may also be difficult to quantify.

Risk and Uncertainty

- Thus, when probabilities of different outcomes are unknown, *uncertainty is transformed into risk;*
- Probabilities of outcomes are subjectively weighted according to their perceived likelihood of occurrence.

What is Risk? 4.

1. Hazard x Exposure;
2. The interaction of *innate characteristics* of a taxon and *environmental features* (sieves) that mediate the interaction;
3. A measure of the completeness of information; and

4. A measure of uncertainty.

A Complex Example

- What is the most difficult challenge to any risk analysis model for biological control?
- Predicting the risk from a natural enemy that attacks, in physiological host-specificity tests, a rare, threatened, endangered, native species in the same subgenus as the target weed.
- Biological control researchers must adhere to tenets of Responsible Conduct of Research.

The Weed: *Heliotropium europaeum*, common heliotrope (Boraginaceae)

- **The biological control agent: *Uromyces heliotropii*, a macrocyclic, autoecious rust fungus (Pucciniaceae).**

Delfosse, Ernest S., Robert C. Lewis and R.C. Hasan. 1995. Release of *Uromyces heliotropii* in Australia: a key agent in the integrated pest management system for common heliotrope. In: Delfosse, Ernest S. and R.R. Scott (eds.) *Proceedings of the VIII International Symposium on Biological Control of Weeds*, 2-7 February 1992, Lincoln University, Canterbury, New Zealand. DSIR/CSIRO, Melbourne, pp. 329-336.

A Complex Example

- Two H_i character states:
  - ✓ H_{phr} = physiological host range; and
  - ✓ H_{bbf} = basic biological features.
- Four E_p character states:
  - ✓ E_{sfh} = susceptible non-target field hosts;
  - ✓ E_{dis} = distribution;
  - ✓ E_{phe} = phenology; and
  - ✓ E_{cli} = climate.

A Complex Example

1. For $H_i = H_{phr}$ = physiological host range:

- **96 species or cultivars in 20 families tested–only the native species *H. crispatum* was attacked (but at a minimal level; see below);**
- **69 immune species (based on historical records) were not tested; and**
- **Plants that supported other *Uromyces* species were also tested without damage.**

- **Hazard prediction: The ecological (field) host range includes only the target weed and *H. crispatum*.**

Hasan, S., Delfosse, Ernest S., and R.C. Lewis. 1992. Host-specificity of *Uromyces heliotropii*, a fungal agent for the biological control of common heliotrope (*Heliotropium europaeum*) in Australia. Annals of Applied Biology 121: 697-705.

A Complex Example

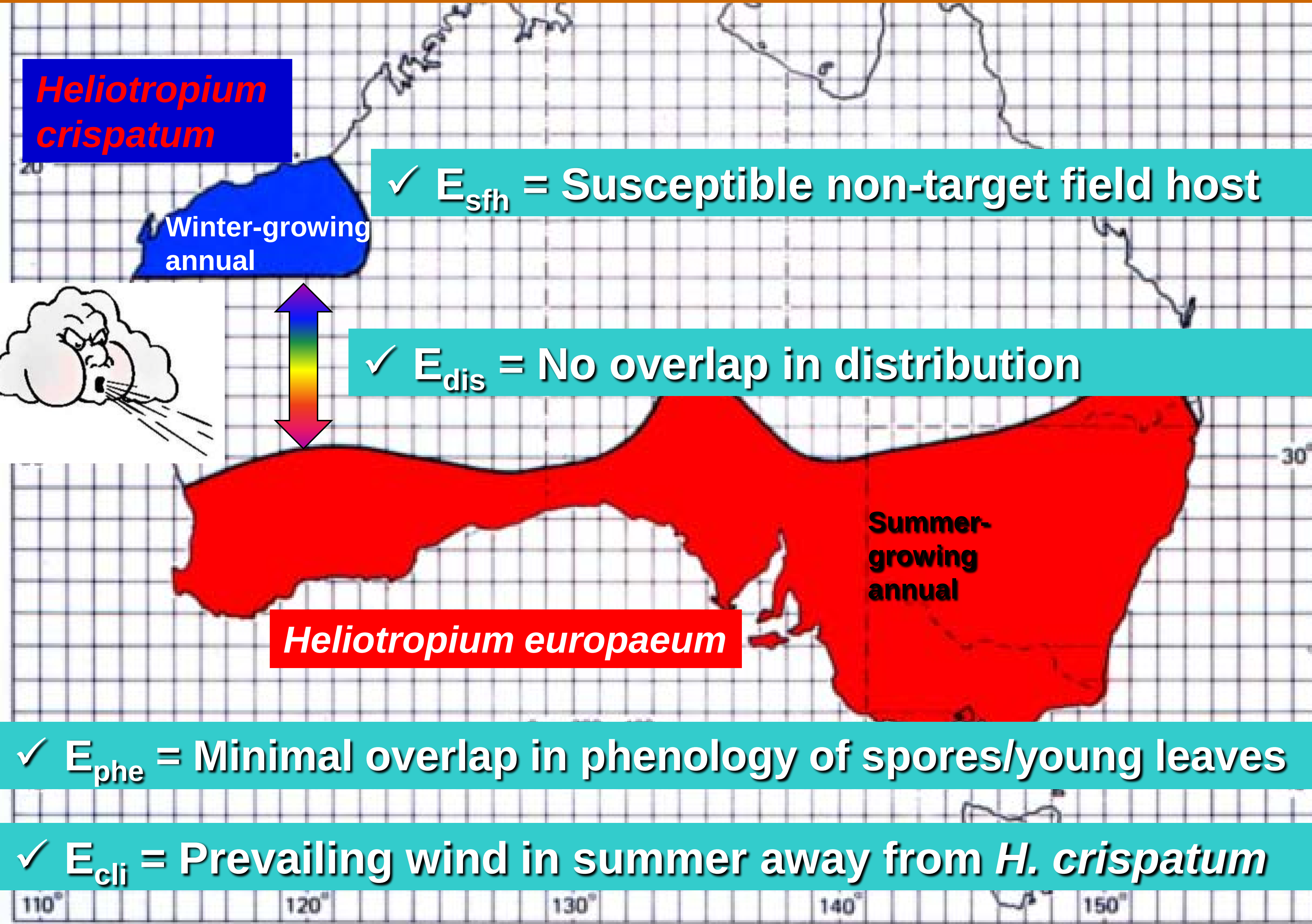
2. For H_i = H_{bbf} = basic biological features:

- **Mycological ecology indicated that a specific temperature-humidity-plant stage relationship is essential to fungal development;**
- **Even under ideal physiological host-specificity conditions, only a few spores were produced only on young leaves of *H. crispatum*; and**
- **These spores cannot reinfect either *H. crispatum* or *H. europaeum*.**
- **<u>Hazard prediction</u>: *H. crispatum* cannot maintain an infection by *U. heliotropii*.**

A Complex Example

- **Four E_p character states (sieves):**
  - ✓ **E_{sfh} = susceptible non-target field hosts (restricted to *H. crispatum*);**
  - ✓ **E_{dis} = distribution of *H. crispatum* (no overlap with *H. europaeum*);**
  - ✓ **E_{phe} = phenology of *H. crispatum* (out-of-phase: summer- vs. winter-growing annuals); and**
  - ✓ **E_{cli} = climate in the distribution of *H. crispatum* during summer, when spores of *U. heliotropii* are produced on *H. europaeum*.**

Exposure analysis for *Uromyces heliotropii*



- ✓ E_{sfh} = Susceptible non-target field host
- ✓ E_{dis} = No overlap in distribution
- ✓ E_{phe} = Minimal overlap in phenology of spores/young leaves
- ✓ E_{cli} = Prevailing wind in summer away from *H. crispatum*

Risk from *U. heliotropii*

- **H_{phr} and H_{bbf} both indicate** ***very low hazard;***
- **E_{sfh}, E_{dis}, E_{phe} and E_{cli} all indicate** ***very low exposure;*** **so**

- **Risk prediction–The risk from *U. heliotropii* to non-target species is very close to zero.**

- **The Good News–*U. heliotropii* was approved for release in Australia.**
- **The Bad News–It didn't work (but the risk analysis model did).**

Risk: A Matrix of Possibilities

Exposure

Hazard		**Low** No species in the same genus	**High** Many species in the same genus
	Low Monophagous or oligophagous agent (e.g., *U. heliotropii)*	**Low Risk**	**Probably Low Risk**
	High Polyphagous agent (e.g., *Dialectica scalariella)*	**Probably Low Risk**	**High Risk**

Risk Analysis of *U. heliotropii*

- **Communication–Australian Quarantine and Inspection Service, the Australian National Parks and Wildlife Service were consulted, State Departments of Agriculture, State pathologists and the funding agencies were consulted early and at several points in the process;**
- **Assessment–96 species or cultivars in 20 families were proposed for testing (much more than was needed to determine risk, but this research was conducted in part to develop the risk model); and**
- **Management–A plan was in place for mediation if necessary.**

Summary and Conclusions

1. **Risk from any biological control agent can be estimated objectively using the model;**
2. **Risk analysis doesn't tell you what to do; you need decision analysis for this (another talk); and**
3. **Regulatory systems that do not incorporate proper risk analysis delay implementation of solutions for serious invasive species.**

It’s Risky, But …

… Any Questions?